K103351

JAN 2 0 2011

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
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Wendy Garman - Contact Person

Date Summary Prepared: November 2010

Device Name:

- Trade Name – DMC Composite 2
- Common Name – Dental Composite Restorative Material
- Classification Name – Tooth Shade Resin Material, per 21 CFR § 872.3690

Devices for Which Substantial Equivalence is Claimed:

- *Premise,* Kerr Corporation
- *Premise Flowable,* Kerr Corporation
- *Optibond Solo Plus 2,* Kerr Corporation

Device Description:

DMC Composite 2 is a self-adhesive, light cured resin based composite dental restorative designed for direct placement. *DMC Composite 2* is offered in both high viscosity and low viscosity formulations, and is indicated for all caries classes. This product contains 82% filler by weight and is radiopaque.

Intended Use of the Device:

DMC Composite 2 High Viscosity is intended for direct restorations of all caries classes. Additional indications include core buildup material, small endo access restorations, repair of porcelain restorations, repair of composite restorations and acrylic restorations, and repair of temporaries.

DMC Composite 2 Low Viscosity is intended for Class I and II (base/liner), Class III and Class V restorations. Additional indications include pit and fissure sealant, repair of enamel defects, repair of porcelain restorations, blocking out of undercuts, minor occlusal build-ups in non-stress bearing areas, incisal abrasions, small endo access restorations, repair of composite and acrylic restorations, and repair of temporaries.

Substantial Equivalence:

DMC Composite 2 is substantially equivalent to other legally marketed devices in the United States. *DMC Composite 2* functions in a manner similar to *Premise* and *Premise Flowable*, marketed by Kerr Corporation, in that it is intended for the repair of all caries classes as well as the repair of composite, acrylic, and porcelain restorations. In addition, *DMC Composite 2* functions in a manner similar to *Optibond Solo Plus 2*, marketed by Kerr Corporation as *Optibond Solo Plus*, in that it is a self-adhesive, light cured resin based composite dental restorative designed for direct placement. The only difference between this 510(k) submission and the original 510(k) submission is the addition of the following new indications for use: Small endo access restorations, repair of composite and acrylic restorations, and repair of temporaries.

Non-Clinical Test Data

Because the addition of the new indications would not result in any formula changes to *DMC Composite 2*, there is no reason to suspect that the safety and biocompatibility of *DMC Composite 2* would be adversely affected.

Clinical Testing

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the similar technological/performance characteristics as compared to the predicate devices, the new indications being added to *DMC Composite 2* are deemed to be substantially equivalent to the predicate devices, *Premise* and *Premise Flowable*, marketed by Kerr Corporation and *Optibond Solo Plus 2*, marketed by Kerr Corporation as *Optibond Solo Plus*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

JAN 20 2011

Re: K103351
Trade/Device Name: DMC Composite 2
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF and EBC
Dated: November 15, 2010
Received: November 16, 2010

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103351

Device Name: *DMC Composite 2*

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103351